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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,068	05/29/2002	Hans Sigrist	Q68066	6054

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20037

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,068

Applicant(s)

SIGRIST, HANS

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The Preliminary Amendment (Paper No. 6) filed on May 29, 2002 has been entered and considered.
2. The disclosure is objected because of the following informalities:

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(i) Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite because it is unclear whether the claim is drawn to a product or a method. Amendment of the claim to clearly recite the invention would obviate the rejection.

(ii) Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite over the recitation of "capable of catalyzing" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited catalytic units have the potential to catalyze or do in fact do catalyze the recited target. Amendment of the claim to read, for example, "which catalyze" would obviate this rejection.

(iii) Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite and unclear for reciting 'variation in a physical parameter via hybridization'. It is unclear what 'physical parameter' refers to i.e. does it refer to nature of binding to a biological molecule or the structural characteristic of the complex formed (complementary nucleotide sequence and biological entity). Further, the instant claim 1 recites 'at least an elementary strand'. It is unclear what this term 'elementary strand' refers to. That is, is it a complementary strand of a DNA molecule or a single-strand RNA or an oligonucleotide?

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Amendment of the claim to clearly recite the physical parameter and elementary strand would obviate the rejection.

(iv) Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for Failing to particularly point out and distinctly claim the subject matter which applicant regards as The invention. Claim 4 recites 'selecting a single kind, by combining several classes or by adding several kinds sequentially'. It is unclear and indefinite what the term(s) 'kind / classes' refer to. That is, do they refer to different enzymes of similar functionality or different enzymes with different functionalities or biotic medium comprising different entities? Amendment of the claim to clearly recite the terms would obviate this rejection.

(v) Regarding claim 1, the word "means" is preceded by the word(s) "measuring" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

(vi) Regarding claim 15, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 1, 9, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinkel et al. (5,690,894).

With reference to the instant claim 1, Pinkel et al. teach a biochemical biosensor comprising plurality of binding partners including nucleotide sequences immobilized on its surface, and sensor surface was fabricated to measure variation in a physical parameter wherein, optical signals produced by biological binding molecules were measured on the sensor surface (see column 3, lines 1-30).

With reference to the instant claim 9, Pinkel et al. teach that the biosensor was characterized in that the sensor surface has a waveguide (optical fiber) which allows optical detection (see column 3, lines 18-30).

With reference to the instant claim 15, Pinkel et al. teach that the biological entity comprises hetero-bifunctional cross-linking agents such as antibody-ligands (biotinylated nucleic acids-antibody)(see column 19, lines 32-43). Thus the disclosure of Pinkel et al. meets the limitations in the instant claims.

B. Claims 1-2, 8, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chai-Gao et al. (USPN. 5,858,802).

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With reference to the instant claims 1-2, Chai-Gao et al. teach a biochemical sensor device or system wherein Gao et al. teach that the device comprises a biosensor for detecting or diagnosing a biological entity, wherein the sensor surface having detection unit comprising photoactivated coupling agent that binds with a biological entity, and the variation in a physical parameter (light emitting or absorption wavelength) which is measured at the biosensor surface (see column 1, lines 57-67, column 7, lines 1-25, column 8, lines 1-15, and column 5, lines 57-67, and column 6, lines 1-34).

With reference to claims 8, 16-17, Chai-Gao et al. also teach that the device comprises monomer compounds as oligonucleotides (see column 8, lines 6-12); compounds allowing the scaffold to be formed include homo- or hetero bifunctional crosslinking agents as immunogloblins (see column 2, lines 9-10, lines 37-51, column 5, lines 6-49).

C. Claims 1-8, and 10-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al. (WO 97/27317).

With reference to the instant claim 1, Lockhart et al. teach a high density arrays (biosensor arrays) comprising probe oligonucleotides immobilized on a solid support (chip) (see page 127, lines 25-32) for detecting and analyzing a biological entity in a biological sample, wherein Lockhart et al. discloses that chip surface comprises detection and measuring means to detect the hybridization signal, a physical parameter, variation in a physical parameter was measured as an indication of biological entity present in the sample (see 90, lines 5-21, page 128, lines 29-31, page 129, 1-24, page 131, lines 10-31, page 132, lines 1-2).

With reference to instant claims 2-7, Lockhart et al. also disclose that the array system includes physical parameter, which could be measured as a light wave or emission of a

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fluorescence signal intensity (see page 37, lines 10-22, page 127, lines 25-36, page 128, lines 1-31, page 129, lines 1-24, page 131, lines 10-31, page 132, lines 1-2); array system comprises DNA end labeling enzyme was a nucleic acid transferase or synthetase (see page 8, lines 3-6, page 131, lines 5-17, see page 107, lines 24-31);

With reference to the instant claims 8, 10-13, Lockhart et al. teaches that monomers of biological entity comprise flurophor label (see page 132, lines 5-24, page 133, lines 8-12, page 135, lines 9-14, page 136, lines 1-31, page 137, lines 1-31); the sequence of nucleotides forming the detection unit was linked to the substrate by covalent bond (see page 29, lines 21-22); the immobilization of the nucleotide sequence on to the surface was carried out by photo-immobilization (see page 63, lines 8-20).

With reference to the instant claims 14-19, Lockhart et al. teaches that the nucleotide sequence forming detection unit indirectly links to the sensor surface via a docking unit which could be via avidin-conjugated flurophore, which complexes with biotinylated target nucleic acid (see page 39, lines 24-31, page 40, lines 1-4); docking unit could include immunogloblins, enzymes, haptens (see page 41, lines 3-12); docking unit comprises partially complementary nucleotide sequence to a corresponding target nucleotide sequence (see page 49, lines 15-31, page 50, lines 1-16). Thus the disclosure of Lockhart et al. meets the limitations in the instant claims.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the

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examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

^{CPC}
Suryaprabha Chunduru
October 18, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER